Supplemental Protocol
Sotrovimab Dosing and Administration

Authorized Use

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product sotrovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Limitations of Authorized Use

- Sotrovimab is not authorized for use in patients:
  - who are hospitalized due to COVID-19, OR
  - who require oxygen therapy due to COVID-19, OR
  - who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity).
- Benefit of treatment with sotrovimab has not been observed in patients hospitalized due to COVID-19. SARS-CoV-2 monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Dosage

The dosage of sotrovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is 500 mg of sotrovimab. Sotrovimab should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset. Sotrovimab must be diluted and administered as a single IV infusion over 30 minutes.

Contraindications

Sotrovimab is contraindicated in patients who have a history of anaphylaxis to sotrovimab or to any components in the formulation.

Fact Sheets

- Provide a copy of the Fact Sheet for Patients, Parents, and Caregivers for sotrovimab and explain risks, benefits and alternatives to the patient, emphasizing that this therapy is not FDA approved but is under Emergency Use Authorization (EUA).
- Review the Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of sotrovimab.

Resources

Refer to Vermont EMS Protocol for COVID-19 Monoclonal Antibody Administration for information on background, eligibility, high-risk factors, equipment, PPE, management of adverse reactions, and documentation.

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Sotrovimab Dose Preparation

- Sotrovimab is supplied in a single-dose vial and must be diluted prior to administration.
- Gather the materials for preparation. Choose from the following:
    - Polyvinyl chloride (PVC) or polyolefin (PO), sterile, prefilled 50-mL or 100-mL infusion bag containing 0.9% sodium chloride injection, or
    - PVC, sterile, prefilled 50-mL or 100-mL infusion bag containing 5% Dextrose Injection, and
    - One vial of sotrovimab (500 mg/8 mL).
- Remove one vial of sotrovimab from refrigerated storage and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes.
- Inspect the vial of sotrovimab visually for particulate matter and discoloration prior to administration. Should either be observed, the solution must be discarded and a fresh solution prepared. Sotrovimab is a clear, colorless or yellow to brown solution.
- Gently swirl the vial several times before use without creating air bubbles. **Do not shake.**
- Withdraw 8 mL of sotrovimab from one vial and inject into the prefilled infusion bag.
- Discard any product remaining in the vial.
- Prior to the infusion, gently rock the infusion bag back and forth by hand 3 to 5 times. **Do not invert the infusion bag.** Avoid forming air bubbles.
- This product is preservative-free, therefore, the diluted infusion solution should be administered immediately. If immediate infusion is not possible, store the diluted solution of sotrovimab up to 6 hours at room temperature up to 25ºC (77ºF) or refrigerated up to 24 hours at 2ºC to 8ºC (36ºF to 46ºF).

Sotrovimab Dose Administration

- Gather the materials for infusion:
- Polyvinyl chloride (PVC) or polyolefin (PO) infusion set, and
- Use of a 0.2 micron polyethersulfone (PES) filter is strongly recommended.
- Attach the infusion set to the IV bag using standard bore tubing.
- Prime the infusion set.
- Administer the entire infusion solution in the bag over 30 minutes. Due to potential overfill of prefilled saline bags, the entire infusion solution in the bag should be administered to avoid underdosage.
- Do not administer as an IV push or bolus.
- The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of sotrovimab with IV solutions and medications other than 0.9% Sodium Chloride Injection and 5% Dextrose Injection is not known.
- Once infusion is complete, **flush the tubing** with 0.9% sodium chloride or 5% dextrose to ensure delivery of the required dose.
- If the infusion must be discontinued due to an infusion reaction, discard unused product.
- Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete.

Storage

Refrigerate unopened vials at 2ºC to 8ºC (36ºF to 46ºF) in original carton. Do not freeze or shake. Protect from light.